

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1-10 are currently pending. Claims 1-9 are directed to derivatives of natural, semisynthetic, and synthetic lipids, in which the derivatives comprise oligomers of ceramides and/or sphingosines. Claim 10 is directed to a pharmaceutical preparation. Reconsideration of the pending claims is hereby requested.

The Amendments to the Claims

The pending claims have been amended to more particularly and distinctly claim the subject matter of the present invention. Specifically, claim 1 has been amended to incorporate features previously recited in former claim 4 with respect to the type of linkage by lipid monomers. In particular, claim 1 has been amended to recite the feature that a cross-linkage of two adjacent lipid monomers is in a “tail-to-tail” arrangement via their hydrophobic fatty acid radical directly or using an intradimeric spacer of freely selectable molecule chain length and composition. Since the remaining pending claims, i.e., claims 2-10, depend from claim 1, all of the claims include these revised features of claim 1. Claim 4 has been revised to be consistent with claim 1 and to further recite that, if present, the intradimeric spacer comprises at least one carbon atom and/or at least one heteroatom (see previous claim 7).

Claims 5 and 6 have been amended to recite features of the “tail-to-tail-arrangement.” Particularly, claims 5 and 6 further recite that adjacent lipid molecules are bonded in a “head-to-head arrangement, via their hydrophobic structural component (claim 5) or via an interdimeric spacer (claim 6). Claim 7 has been revised to recite that the intradimeric spacer is predominantly hydrophilic. Claim 8 depends from claim 6 and recites that the interdimeric spacer contains structural components of certain recited compounds (see, e.g., original claim 11). Claim 9 recites the feature that adjacent lipid molecules are bonded in the “tail-to-tail” arrangement via the ω -position carbon atom of the fatty acid chain, by a covalent bond. Claim 10 has been transformed to recite a pharmaceutical preparation. Claims 11-16 have been canceled. No new matter has been added by way of these amendments.

Summary of the Office Action

Claims 1-12, 15-16 have been rejected under 35 U.S.C. § 103(a) as obvious over Yedgar (i.e., U.S. Patent No. 7,393,938).

Discussion of the Obviousness Rejection

The prior art rejections are premised on Yedgar. However, the revised pending claims render the prior art rejections moot since Yedgar does not meet the features of the revised pending claims.

The revised pending claims recite lipid oligomers, in particular lipid dimers which are coupled in the so-called tail-to-tail-arrangement of the hydrophobic regions of the lipids.

Yedgar (formulas I to XXI) and its parent patent -- U.S. Patent No. 7,034,006 (formulas I to X) -- only teach compounds being coupled in the *hydrophilic* region of the phospholipid. Both documents therefore do not disclose or suggest coupling of the lipid in the *hydrophobic* region according to the present claim 1.

It is important to note in this context that a purpose of the invention is to provide lipid oligomers which indicate the lipid bilayer which can be found in organisms.

It was found that a direct coupling of the lipids or a coupling via a spacer is possible. However, for the mentioned purpose, only small spacer molecules are suited to realize a comparable structure to the natural bilayer.

A detailed analysis of the prior art documents shows that this requirement is not fulfilled by the components mentioned therein since the coupling of the hydrophilic regions of the lipids will not result in the teaching of the present claim 1.

As outlined by the general formula (II) of Yedgar, a phospholipid (containing the two fatty acid residues R₁ and R₂) is linked with its phosphate group to a serine moiety (using the hydroxy group of the same), which is linked to a non-specifically determined spacer group ranging in length from 2 – 30 carbon atoms. The arising moiety finally is linked to a glycosaminoglycan.

It is evident that the molecular moiety “phospholipid-serine-spacer” does contain only one single unit of each molecular species. Thus, per definition, these moieties are not dimers, tetramers, oligomers or polymers of phospholipids (or, in general, lipids).

In addition, the molecular moiety “phospholipid-serine-spacer” is linked to a physiological molecule of the type of glycosaminoglycans.

The glycosaminoglycans are biological molecules comprising hyaluronic acid, heparin, heparan sulfate, keratin, keratan sulfate, dermatan sulfate or a derivative of dermatan sulfate. The basic structure of glycosaminoglycans are disaccharide or trisaccharide units covalently bound together forming chains of monomers, dimers, trimers, oligomers or polymers containing the saccharide units in numbers of 1 up to 1,000. Furthermore, the said disaccharide or trisaccharide units are 6-membered ring systems (disaccharides containing two rings, trisaccharides containing three rings).

According to the general formula II, the molecular moieties “phospholipid-serine-spacer” are linked to the said glycosaminoglycans using the hydroxyl or amino groups present in the said molecules for the link. Because of the abundance of these linking groups in the said glycosaminoglycans, a large number of “phospholipid-serine-spacer” moieties can be linked to the glycosaminoglycan molecule thus finally forming a molecule comprising of a glycosaminoglycan *backbone* linked with a large number of phospholipid-serine-spacer *side chains*.

Thus, the basic structure of the compounds represented in general formula II differs in the following structural features and entities from the compounds claimed in the present invention.

Moreover, as clearly shown in general formula XII (column 23), the ceramide is linked to a small molecule “Z” (ethanolamine, serine, inositol, choline, or glycerol), furtheron linked to a spacer “Y” in length from 2 to 30 atoms. This “phospholipid-serine-spacer” moiety is linked to a physiological molecule of the type of glycosaminoglycans. Assuming the most simple case that the said glycosaminoglycan is a disaccharide monomer (not a dimer, oligomer or polymer), the complete structure of the resulting molecule is e.g.:

ceramide – ethanolamine – spacer – disaccharide – spacer – serine – ceramide

Even if ethanolamine and serine and the spacer is omitted in the cases in which Z and Y is “nothing,” the resulting molecule could be:

ceramide – disaccharide – ceramide.

However, also in this case, the disaccharide spacer is coupled with the hydrophilic regions of the lipids, i.e. next to the phosphorous group.

In consequence, since the prior art documents neither offer any advice for the skilled person for a coupling of the lipids in the hydrophobic region nor for the inventive purpose, the present set of claims is not obvious for the skilled person.

Since the cited reference does not disclose or suggest the subject matter of the revised pending claims, Applicants respectfully suggest that the prior art rejections be withdrawn and the application allowed.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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